

UNITED STATES OF AMERICA

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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TECHNICAL ELECTRONIC PRODUCT RADIATION SAFETY
STANDARDS COMMITTEE

+ + + + +

28th Meeting

+ + + + +

Thursday,

May 17, 2001

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The Committee was called to order at 8:30 a.m., at the Food and Drug Administration, 9200 Corporate Boulevard, Suite 01-02, Rockville, Maryland 20850 by Chairman Larry Rothenberg, presiding.

PANEL MEMBERS PRESENT:

DR. LARRY ROTHENBERG, Chairperson
DR. ORHAN SULEIMAN, Executive Secretary
DR. DAVID N. LAMBERT, Member
LTC MICHELE LOSCOCCO, Member
DR. JOHN M. SANDRIK, Member
DR. ALICE FAHY-ELWOOD, Member
DR. MAUREEN MURDOCH NELSON, Member
DR. MARY V. MARX, Member
DR. JOHN F. CARDELLA, Member

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PANEL MEMBERS PRESENT: (cont.)

MR. ROBERT PLEASURE, Member
CPT JERRY A. THOMAS, Member
DR. WILLIAM R. RICE, Member
DR. GREGORY W. LOTZ, Member
DR. QUIRINO BALZANO, Member
DR. STEVE SZEGLIN, Member
MS. KATHLEEN A. KAUFMAN, Member

PUBLIC SPEAKERS:

MS. LILLIAN GILL
DR. W. HOWARD CYR
DR. RONALD KACZMAREK
DR. TOM SHOPE
DR. STANLEY STERN
DR. ROBERT GAGNE
MR. COLLIN FIGUEROA
DR. RUSSELL OWEN

C-O-N-T-E-N-T-S

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P-R-O-C-E-E-D-I-N-G-S

(8:30 a.m.)

SECRETARY SULEIMAN: I would like to get the meeting started. I am Orhan Suleiman, Executive Secretary for the Technical Electronic Product Radiation Safety Standards Committee, and I want to read something quickly here, and then have an introduction and some comments by Dr. David Fiegall, who is the Center Director, and get into the agenda early. Actually, why don't you go ahead and welcome people and I will begin right after you.

DR. FIEGAL: I just wanted to come this morning and welcome you to today's meeting. As Orhan likes to remind me, this is the oldest standing committee now that the T-Board has disappeared. And it is one that we value very much.

You know, in today's agenda, I think it really illustrates the need for continued vigilance and attention to the area of radiological safety, and health, and we will hear today about both very new technologies and some of the issues with safety as to that, and we will also hear about problems we may have

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1 thought have largely been solved.

2 Ad who would have thought that we would be
3 once again coming back to issues around philosophy,
4 and there have been times when there have been
5 problems with that, and where it seems to increase and
6 the difficulties arising from that.

7 Also today, we will share with you --
8 Lillian Gill, who is the Deputy for Science for the
9 Center, will share with you some of our thoughts about
10 the future of the Rad program and CDRH is one that has
11 changed over the years, and we appreciate your
12 thoughts about what the challenges of the future will
13 be.

14 There have been focuses that have been
15 taken in the past to assure the safety of these
16 products, but there have been many changes in the some
17 30 years since the Center for Devices and the Rad
18 Health Program with the Public Health Service merged
19 in a way that they are manufactured, and in the way
20 the whole economy works has made this a very
21 challenging environment.

22 It is a very challenging environment to be

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1 a national regulatory body in a global economy.
2 Globally, the whole trends are to take down borders
3 and to have free trade, and have rapid interchange
4 together.

5 A lot of our premises of structure in
6 regulatory programs would be that we would have strong
7 input from Rads, and we would have a great deal of
8 national manufacturing, and things which have rapidly
9 changed.

10 So let me again welcome you and thank you
11 for taking the time from your busy schedules to come
12 and advise us, and to help us. It is important not
13 only for your expertise, but also that this be a
14 public process, and it is a process that has a record,
15 and one that has developed over time.

16 And I told Orhan that even though I had a
17 meeting across town, I did want to stop and thank you
18 for coming and wish you a product day. Thanks very
19 much.

20 SECRETARY SULEIMAN: Thank you, Dr.
21 Fiegall. Let me read the formal statement that I need
22 to make. In accordance with the Radiation Control for

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1 Health and Safety Act of 1968, Public Law 90-602, the
2 Secretary of the Department of Health and Human
3 Services has established a Technical Electronic
4 Product Radiation Safety Standards Committee, known as
5 TEPRSSC, for consultation on matters relating to
6 technical electronic product radiation safety.

7 As specified by Public Law 90-602, the
8 Committee consists of 15 members, including the
9 Chairman, who are appointed by the Commissioner of
10 Food and Drug, with overlapping terms of four years or
11 less.

12 Five members are selected from
13 governmental agencies, including State and Federal
14 Governments; five members from the affected
15 industries, and five members from the general public,
16 or at which least one shall be a representative for
17 organized labor.

18 Members must be technically qualified by
19 training and experience in one or more fields of
20 science or engineering applicable to electronic
21 products, radiation safety, and standards.

22 The primary function of TEPRSSC is to

1 provide advice and consultation to the Commissioner of
2 Food and Drugs on the technical feasibility and
3 reasonableness of performance standards for electronic
4 products; to control the emission of electronic
5 product radiation from such products; and to review
6 amendments to such standards before being prescribed
7 by the Commissioner.

8 The committee is not requested to review
9 individual applications for particular products,
10 specific products. Public Law 90-602 and its
11 legislative history clearly indicated that the
12 TEPRSSC members are expected to represent a very wide
13 range of interests, with at least one-third of the
14 committee nominated by the regulated industry itself,
15 and appointed on the basis their being able to
16 represent industry-wide concerns.

17 Section 534 of the Federal Food, Drug, and
18 Cosmetic Act specifies that TEPRSSC members are not to
19 be considered officers or employees of the United
20 States for any purpose, including conflict of interest
21 determinations.

22 However, to be consistent with FDA's

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1 general policies regarding advisory committees, the
2 agency believes that a public disclosure memorandum
3 should be made a part of the public record, which
4 identifies each member and provides their appointment
5 affiliation.

6 Approved on September 15th and September
7 23rd, 1998, August 30th, 1999, and June 9th, 2000, be
8 delegated authority of the Commissioner of Food and
9 Drugs, the members of TEPRSSC are -- and I will read
10 their names quickly here.

11 Representing the General Public, John
12 Cardella, M.D., State University of New York, Syracuse
13 Health Science Center; Mary Marx, M.D., University of
14 Southern California; Robert Pleasure, J.D., The Center
15 to Protect Workers' Rights; William Rice, M.D.,
16 American Radiology; Lawrence Rothenberg, Memorial
17 Sloane-Kerric Cancer Center.

18 Representing the Government is Kathleen
19 Kaufman, Los Angeles County Department of Health
20 Services; Michele Loscocco, Lieutenant Commander,
21 Joint Readiness Clinical Advisory Board; Gregory
22 Lotz, Ph.D., National Institute for Occupational

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1 Health and Safety; Maureen Murdoch Nelson, M.D.,
2 Veterans Administration Medical Center; Captain Jerry
3 Thomas, Uniformed Services of the Health Sciences.

4 And representing Industry are Quirino
5 Balzano, Ph.D., Motorola Florida Laboratories,
6 recently retired; Alice Fahy-Elwood, with Lucent
7 Technologies, New Jersey; David Lambert, Ph.D.,
8 Lambert Systems; John Sandrik, Ph.D., General Electric
9 Medical Systems; and Steven Szeglin, PGW, a New York
10 Corporation.

11 I welcome you here, and I would like to
12 pass off to Dr. Larry Rothenberg, who is the Chairman.

13 CHAIRMAN ROTHENBERG: Thank you, Orhan.
14 I would also like to welcome everyone here. I would
15 like to thank the members of the committee for taking
16 time out from their busy schedules to be here, and to
17 the members of the Center staff who have prepared and
18 organized the meeting for this morning.

19 I thought it would be a nice idea to start
20 out and if we could just go around the table and have
21 each of the committee members say a second or two
22 about their activities and interests, and I will start

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1 out.

2 I am a medical physicist at Memorial
3 Sloane Ketter Cancer Center, with a primary interest
4 in activities related to diagnostic radiology, and in
5 particular computed tomography and mammography, as
6 well as other areas,

7 DR. LAMBERT: I am David Lambert, and I am
8 a Professor in Electrical and Computer Engineering at
9 Carnegie-Mellon University, and my primary interests
10 are in the field of magnetism and electromagnetism,
11 and I work extensively in the field of data storage.

12 DR. SANDRIK: John Sandrik, G.E. Medical
13 Systems, and I am a medical physicist, working
14 primarily in mammography right now, with some
15 responsibility in general diagnostic radiology.

16 DR. ELWOOD: I am Alice Fahy-Elwood, with
17 Lucent Laboratories, and I am primarily involved with
18 non-ionizing radiation safety associated with wireless
19 and optical products.

20 DR. NELSON: I am Maureen Murdoch Nelson,
21 and I am affiliated with the Minneapolis VA Medical
22 Center, and my interest is in research design and

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1 evaluating research.

2 DR. MARX: I am Vicky Marx, a
3 interventional radiologist, at U.S.C., in Los Angeles,
4 and I represent the Occupationally exposed.

5 DR. CARDELLA: Good morning. My name is
6 John Cardella, and I am currently the Chairman of
7 Radiology at the State University of New York, and by
8 training, I am an interventional radiologist, and most
9 recently have been interested in standards writing for
10 radiation safety, and new equipment and design.

11 DR. RICE: Good morning. I am William
12 Rice, a diagnostic radiologist, in Baltimore, American
13 Radiology. I am particularly interested in
14 mammography.

15 DR. LOTZ: I am Greg Lotz, with CDC's
16 National Institute for Occupational Safety and Health,
17 in Cincinnati. I have a background in biophysics and
18 physiology, with a particular interest towards
19 biological effects of non-ionizing radiation.

20 DR. BALZANO: I am Quirino Balzano,
21 formerly with Motorola, and I was involved for a long
22 time in the design of cellular telephones, and my main

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1 interest was with imagery and radio frequency and
2 laboratory.

3 DR. SZEGLIN: Steve Szeglin, PTW. I am
4 a medical physicist, and my main area of interest is
5 ionization chamber, electrometer design.

6 MS. KAUFMAN: I am Kathleen Kaufman, and
7 I am the Director of the Los Angeles County Health's
8 Radiation Management Program, and we assure compliance
9 with regulations and radiation safety for 350
10 radioactive materials licenses, and about 18,000 x-ray
11 tubes.

12 CHAIRMAN ROTHENBERG: Again, I would like
13 to thank you all for being here. Our next item of
14 business is Ms. Lillian Gill, who is the CDRH's deputy
15 director for science, will give us an update of
16 informal issues.

17 MS. GILL: Good morning. I have not been
18 formally knighted the deputy director for science. I
19 am acting in the place of Dr. Jacobson, who as we
20 heard recently is retiring from the FDA soon.

21 I want to give you an update on many of
22 the issues that were under discussion before this

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1 panel not only last year, but some of these were
2 discussed in previous years as well.

3 These will be -- I will be giving you sort
4 of a status report on the fluoroscopy amendments, the
5 proposed amendments to the laser standard, the sunlamp
6 issues on the sunlamp standard, people scanners, the
7 t.v. receivers, and ultrasound.

8 And I would also like to give you just a
9 brief update on where we are with our revitalization
10 project for radiological health issues. Although our
11 agenda doesn't call for discussion of these issues,
12 our subject matter experts are available for questions
13 and are certainly here throughout the day.

14 In the area of the fluoroscopy amendments
15 to the CDRH performance standard for diagnostic x-ray
16 systems, our efforts to publish the proposed
17 amendments to the performance standards continue.
18 These amendments, primarily addressing fluoroscopic x-
19 ray systems, have been discussed as I said before in
20 prior meetings.

21 Since the June 2000 meeting, since last
22 year, our working group developing this proposal has

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1 completed the required draft impact assessment
2 statement which focuses on the potential costs and
3 benefits of the proposed amendments, as well as on the
4 effects of the proposed action on the human
5 environment.

6 In July of last year that draft assessment
7 was provided to the industry and posted on our website
8 with a request for comments. We received no
9 substantial comments of this assessment. So we
10 refined the document and incorporated into the draft
11 notice of proposed rule making some of those
12 refinements.

13 In December of last year, the Center
14 approved the draft Federal Register notice, which was
15 reviewed by the Office of Chief Counsel in FDA and
16 commented on. We are in the process really of
17 incorporating their comments, after which the document
18 will be returned to them for final clearance.

19 It will undergo some further editing. We
20 will need the signatures of the Commissioner's
21 Office, and then we will have and hopefully receive
22 final clearance at the department level.

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1 So although the proposed amendments are
2 not yet published, the publication of the notice of
3 proposed rule making is anticipated this year, for
4 which we will have 120 day comment period.

5 After this deadline the comments will be
6 considered by Agency staff, and will proceed with the
7 final rule, which would become effective one year
8 after its publication.

9 So on our current time line, these
10 proposed rules should become final sometime in early
11 2003. And on the issue of our proposed amendments to
12 the laser standard, for your last meeting, Mr. Jerry
13 Dennis provided you with a preliminary draft of these
14 proposed amendments.

15 The purpose of these amendments, if you
16 will remember, was to harmonize many of the
17 requirements of the FDA standard with the pending
18 revisions to the International Electrotechnical
19 Commission, or the IEC Standard 60825-1, and with a
20 60601-2-22 Standard.

21 At that time the amendments to the IEC
22 60825-1 were out for a vote. Your advice to us was to

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1 continue without waiting for the IEC ballot. Your
2 reasoning was at that time that even if the IEC
3 amendments were not approved, they would probably be
4 included with similar effect in the next IEC ballot.

5 As it turned out the IEC amendments were
6 unanimously approved in October of last year and
7 published this past January. If you will remember the
8 focus of those amendments was the incorporation of
9 some recent photobiological scientific data, and the
10 creation of a new hazard classification scheme for
11 laser products.

12 The cornerstone of that was the
13 restructuring of the hazard classes and really the
14 creation of a new product hazard class that takes into
15 account the design of the optical instruments that are
16 used to view laser radiation.

17 Since your last meeting the draft proposed
18 CDRH amendments, and the preamble, have been
19 completed, as well as a concept paper. A guidance
20 document has also been drafted for use while our
21 amendments are going through the process of approval.

22 This guidance states that we will not

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1 object to laser products that do not comply with some
2 of our requirements if they comply with the comparable
3 requirements of the IEC standards, such as
4 classification.

5 In the area of sunlamp standards last
6 year, we presented five possible changes to the FDA
7 performance standard for sunlamp products. This
8 presentation came after a review of comments that were
9 obtained as a result of our publishing an advanced
10 notice of proposed rule making.

11 A review of that ANPRM and its comments,
12 I believe, are included in your briefing package. FDA
13 concluded that some of the possible changes that were
14 presented in that ANPRM needed more research data, and
15 more analysis before formal presentation before the
16 Board, or the advisory panel. I'm sorry.

17 Therefore, we narrowed our possible
18 changes to five. One, the establishment of the
19 existing recommended exposure schedule as part of the
20 performance standard itself.

21 Two, the use of the human cancer action
22 spectrum in a manner similar to that used by the

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1 International Electrotechnical Commission. Three,
2 requiring those that make significant changes that
3 affect performance of sunlamps, or sunbeds, to assume
4 the responsibility of manufacturers.

5 Four, to require a simpler, easier to
6 read, warning label; and the last, to require warning
7 labels in catalogs, specification sheets, and
8 manufacturer's brochures.

9 FDA felt that these changes would be the
10 easiest to implement and would be relatively
11 uncontroversial. At our last meeting, at the last
12 TEPRSSC meeting, representatives from the indoor
13 tanning industry, if you will remember, disagreed with
14 our proposals, suggesting that more analysis should be
15 done before proceeding with any specific proposals.

16 TEPRSSC advised FDA at that meeting to
17 meet with the affected industry to discuss these and
18 any other proposals to better understand the issues
19 before returning to the panel with another round of
20 possible changes to our performance standard for
21 sunlamp products.

22 Since that time the FDA has met with

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1 members of the indoor tanning industry. We met with
2 them on September 13th, 2000. Each of the issues of
3 concern were discussed in detail, and a better mutual
4 understanding of the issues was reached.

5 Summaries of the proceedings of the
6 September 13th open meeting have been written by the
7 industry trade journals, and are on several industry
8 related internet sites.

9 We are also having additional
10 opportunities for the exchange of scientific
11 information during the upcoming months. On June 7th
12 and 8th, we have a meeting of the national and Federal
13 councils on skin cancer prevention at NIH.

14 At that time, medical, academic,
15 government, and non-government representatives will
16 consider research, regulation, and educational efforts
17 pertaining to skin cancer.

18 Following this, on June 9th and 12th, is
19 the effects of light symposium in Boston, where FDA
20 will present results of its research on methods for
21 measuring changes in human skin following UV
22 exposures.

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1 Then in mid-July, our experts will attend
2 the American Society for Photobiology's 29th annual
3 meeting in Chicago. Dr. Janusz Beer will participate
4 in the session, entitled, "Burning, Tanning, and
5 Typing."

6 And Mrs. Sharon Miller and Dr. Howard Cyr
7 will address optimizing exposure schedules and
8 sources. Meanwhile, we will continue to evaluate the
9 numerous responses that we received from the ANPRM and
10 from any subsequent meetings with the medical
11 community and the indoor tanning industry.

12 And then propose specific amendments to
13 the current performance standard. These amendments
14 will be based on the current best science of the
15 documented bio-effects of UV. These amendments will
16 also bring the current regulations up to date.

17 However, as we all realize, the regulatory
18 process is never static. New amendments will in-turn
19 also be subjected to change and a better understanding
20 of the science of UV effects and better assessment of
21 the risks associated with UV exposures to sunlamps are
22 developed.

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1 On people scanners, the FDA doesn't
2 currently have mandatory standards for security
3 screening systems that utilize ionizing radiation.
4 This is a new technology applied to an old concept as
5 the intentional exposure of people for non-medical
6 purposes has been considered unacceptable in the
7 latter half of the past century.

8 To address the wide spectrum of opinion on
9 the subject, and the lack of guidance for regulators
10 in the industry, the American National Standards
11 Institute, or ANSI, N-43 committee appointed a
12 subcommittee to draft a consensus standard for the
13 security screening of people.

14 Two of our Center staff are on this
15 committee, Frank Saraous serves as the Chair, and Dan
16 Cassidy, in the Office of Compliance, is also a
17 member. That committee, the N43.17 subcommittee, has
18 held three meetings since last year's TEPRSSC meeting,
19 and resulted in as many drafts.

20 The first two meetings were held in
21 Rockville on August 28th and August 29th, and in mid-
22 November, November 13th and 14th. The last meeting

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1 was held at the Health Physics Society, and they are
2 meeting in Anaheim, California, in February.

3 While in California, that subcommittee
4 also visited the U.S. Customs and observed the
5 operation of a body scanner at the Los Angeles
6 Airport, as well as toured the Rad scan (phonetic)
7 plant in Hawthorne, where security scanners are
8 manufactured.

9 Radiation surveys of different models of
10 standards are made at both locations. Prior to the
11 subcommittee meeting a presentation on the status of
12 the standard was given at the health physics society
13 media conference, and that talk was well received by
14 those in attendance, and no objections to any part of
15 the draft standards were voiced.

16 That Anaheim meeting was meant to be the
17 last meeting before submitting a final draft to the
18 main committee. However, holding that meeting on the
19 West Coast and in conjunction with the HPS conference
20 allowed for participation by some attendees not at the
21 previous two meetings.

22 As a result of that, some topics were

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1 revisited and discussed at length, resulting in some
2 additional changes. The main changes consisted
3 primarily of removal of the explanatory discussions
4 from the body of the standard to an appendix, to a new
5 appendix, and the replacement of required operator
6 limits with the discussion of operator doses and
7 pertinent recommendations.

8 This last change was done and was
9 necessary to be consistent with the OSHA and the
10 Nuclear Regulatory Commission's regulation for
11 allowable doses to radiation workers.

12 The main work that remains to be done in
13 this area is to incorporate these changes that have
14 been agreed upon by the subcommittee. It is hoped
15 that this work can be finalized by E-mail and we won't
16 have to have another meeting.

17 If so, the draft will then be submitted to
18 the main N43 committee for comment and balloting.
19 This is somewhat behind our planned schedule, which
20 was December 2000. However, the planned publication
21 date of June 2002 remains the goal of the
22 subcommittee.

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1 In the area of television receiver, and
2 the television receiver standard, we are planning for
3 some collaborative training. Our center and ORA,
4 which is part of FDA's Winchester Engineering and
5 Analytical Center, together with the consumer
6 electronics association, are planning to sponsor a
7 course to train manufacturers' personnel on the
8 Federal requirements for television products under
9 Chapter 5 of the Food, Drug, Cosmetic Act.

10 FDA and CEA have developed videotapes for
11 the course, which emphasize compliance with the
12 performance standards for television receivers in
13 Section 1020.10 of Title 21 of the Code of Federal
14 Regulations, as well as the procedures for testing
15 products for compliance.

16 An ultrasound, as you may recall, last
17 year the FDA presented a pilot to the TEPRSSC
18 committee for comment. We proposed the use of a
19 voluntary international consensus standard, along with
20 the medical device regulatory requirements, in lieu of
21 a mandatory radiation performance standard for
22 ultrasound diathermy products.

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1 As an update of where we are on the pilot,
2 we are now working out the internal processes and
3 policies for that pilot. We hope to have a guidance
4 issued following our mandated need to clear it through
5 good guidance practices by next fall when the next
6 batch of standards will be recognized for use by the
7 medical device industry.

8 And lastly our efforts on revitalizing
9 radiological health per the radiological health
10 program and CDRH, over the past several years, we have
11 briefed you on the progress of CDRH's reengineering
12 projects, including the revitalization of the Rad
13 health program.

14 Since the last TEPRSSC meeting, we have
15 held an open public meeting in November to discuss our
16 proposed prioritization model and explore other
17 improvements in information exchange, standards, and
18 product testing.

19 The results of this meeting support our
20 approach to prioritization. They support our role as
21 an information clearing house, which includes
22 establishing Federal agency alliances, training

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1 alliances, and holding periodic meetings with
2 stakeholders.

3 It includes a recommendation for
4 simplifying and harmonizing standards, and providing
5 training and guidance documents to supplement or even
6 substitute for some standards, and it includes a
7 recommendation for improvements in product testing,
8 such as an orphan instrument development program, and
9 workshops with test labs to modify and simplify
10 testing.

11 The summary of the open public meeting is
12 posted on our website under special topics
13 reengineering. We have had over the past couple of
14 months a strategic planning effort underway in CDRH,
15 and many of our reengineering activities, including
16 the Rad health reengineering activities, are being
17 folded into the Center's strategic plan, so that many
18 of these recommended changes become incorporated in
19 our daily activities and our plans. And that
20 concludes my remarks. Thank you.

21 CHAIRMAN ROTHENBERG: Thank you very much,
22 Ms. Gill, for your comprehensive update of informal

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1 issues and activities. Maybe at this time, do any of
2 the committee members have any questions or comments
3 for Ms. Gill?

4 MS. KAUFMAN: Kathleen Kaufman. I have a
5 comment and a question. I wanted to clarify one
6 thing, because on the people security scanners, you
7 had mentioned something about the workers meeting the
8 Nuclear Regulatory Commission's exposure limits for
9 occupational workers.

10 And it actually appears that what they are
11 moving towards or what they are at this point advising
12 is that they meet the records for the members of the
13 public, and not for occupational workers.

14 But I had a question on the sun lamp
15 proposals. Unfortunately, I read most of this book
16 before I left, but this was one section that I read on
17 the plane.

18 So I didn't have my previous year's
19 notebook. And I was wondering if they are down to
20 five proposals, but what I couldn't recall is if there
21 are proposals that have now been eliminated, and if we
22 might briefly here what FDA is no longer considering.

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1 MS. GILL: I am going to have our sun lamp
2 expert revisit any that have been eliminated.

3 DR. CYR: Yes, there were. I am going to
4 have to scratch my brain here and try to remember what
5 they were, but there were some issues with which we
6 originally proposed, which upon examination were not
7 resolved scientifically, and we are just are going to
8 have to wait for more data to come in.

9 And I am trying to remember what some of
10 those are now. I don't have my notes in front of me
11 from then, and this is about 3 years ago.

12 MS. KAUFMAN: Well, let me ask the
13 question, because was there some discussion previously
14 about requiring specific warnings to be provided to
15 customers, to the users of the equipment? In other
16 words, right now it is talking about warning labels
17 and catalogs.

18 DR. CYR: Right.

19 DR. LAMBERT: And specification sheets,
20 and manufacturer's brochures. But I thought
21 originally there had been some discussion about what
22 would be provided to the customers.

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1 DR. CYR: Well, that would be nice, but
2 that is something that is done at the State or local
3 level. The actual regulations of the salons, per se,
4 is not in our domain. We regulate the manufacturers
5 of the lamps and the tanning beds.

6 MS. KAUFMAN: There was never ever any
7 requirement that specific language be provided to
8 users?

9 DR. CYR: We have worked with the National
10 Council of Radiation Control Program Directors, and
11 have come up with language as part of that group that
12 should be given to, let's say, clients of a tanning
13 salon. And it is basically a rewording of the same
14 warning that is on the tanning beds themselves.

15 So that the clients coming in knows what
16 the risks are, and reads that, and then perhaps even
17 signs an informed consent statement. I do recall now
18 one of the most contentious issues, and that was would
19 there be a melanoma warning, per se. Would there be
20 a warning of melanoma.

21 And the science behind that changed in the
22 last 3 or 4 years. About three years ago when this

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1 came up, that was really a hot issue. There were a
2 couple of major studies that had come out, and one of
3 them was an epidemiology study out of Sweden linking
4 an increase in melanoma with sunlamp use.

5 And a second one was a study involving
6 fish of all things, and in which they had looked at
7 the induction of melanoma or the production of
8 melanoma in this particular model of fish, because
9 there are actually very few animals that actually get
10 melanoma. Humans are one of the few that get it, and
11 this particular little fish is also one of those.

12 And they were concerned because there was
13 far more melanoma production in the UVA range, longer
14 wavelengths of UVA, than one would expect if you had
15 just looked at let's say the action spectrum for
16 erythema.

17 So it seemed to be far more effective in
18 producing melanoma than it was in producing erythema.
19 Now, since that time there have been other studies and
20 the issue or the epi story is not as clear cut as
21 that.

22 There are plenty of other epi studies that

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1 don't show this connection with sunlamps. There are
2 some that do, but it is just not a clear cut
3 epidemiological conclusion on that. One thing is,
4 too, that melanoma appears on parts of the body where
5 the sun doesn't shine. So it is not as clear cut as
6 this for basal or spring carcinoma.

7 DR. RICE: Has there been any
8 consideration for a training program for the
9 operators? Is that a --

10 DR. CYR: Yes. We have worked before with
11 the States in training programs, and most of that
12 training has been done by our Office of Compliance on
13 how to train inspectors for the most part. Training
14 of actual salon operators and those who run the
15 machines themselves is again probably more of a State
16 issue.

17 And we work again with the Council on
18 Radiation Control Program Directors and trying to get
19 those programs set up. The industry itself has been
20 fairly active in the last year or year-and-a-half in
21 trying to get training programs. And they have even
22 talked about certification of operators and of tanning

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1 salons. So there has been some movement on training
2 in the last year or year-and-a-half.

3 MS. KAUFMAN: So there is nothing that you
4 recall that was eliminated that was something that --

5 DR. CYR: Well, the melanoma warning, per
6 se, no.

7 MS. KAUFMAN: A melanoma warning?

8 DR. CYR: Yes, because there was a strong
9 push for a melanoma warning, per se, into the
10 standard, and based on as I said the uncertain
11 epidemiology studies, et cetera, and also critiques of
12 the fish study, and what does it really mean.

13 There is differences in skin thicknesses,
14 and differences in repair enzymes, et cetera, where it
15 is very, very hard to interpret what happens in the
16 fish and what happens in a human.

17 Since that time also there has been not an
18 actions spectrum of another model, on a mammalian, but
19 actually on almost a single point, the induction of
20 melanoma in a rodent model worked on by Ron Layne in
21 New Mexico; and his data showed that melanoma fell
22 somewhere in between what Dick Setlo had found for the

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1 fish model, and what one would expect from looking at
2 an erythema action spectra.

3 And so it was not as bad as the fish
4 model, but then again it was not as good as erythema.
5 So the action spectra story is still up there in the
6 air as to what is really going on with UVA and
7 melanoma.

8 DR. CARDELLA: I am curious in terms of
9 the ongoing meetings that are being held in between
10 TEPRSSC meetings about this issue of sunlamps. And
11 the specific concern is the representation or the
12 information being obtained balanced as the American
13 Academy of Dermatology continues to be involved in
14 this, or is it strictly meetings with industry people?

15 Are there meetings with those that
16 originally raised those concerns?

17 DR. CYR: Well, we have talked to the
18 Academy of Dermatology, and asked them to some of
19 these meetings, and their participation has not been
20 as great as has been the industry. I guess the
21 industry is far more interested in it than now the
22 dermatology community.

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1 So it has been a little heavy on the
2 industry side. We can make a more concerted effort to
3 make sure that dermatology people know about these
4 meetings, and try to send somebody to them.

5 The best way for me to do that is through
6 this Federal Council, because the dermatology
7 community is at those meetings, and I have tried my
8 darnest to tell them about these meetings and what the
9 issues are, and put it into the minutes, and hope that
10 somebody shows up.

11 They do, but again not in the same numbers
12 or with the same intensity as the industry has
13 participated.

14 DR. NELSON: And along that line, I was
15 wondering if maybe members of this committee might
16 participate in some of these meetings. I don't know
17 if that is a conflict of interest or not.

18 DR. CYR: Well, that is a good point, and
19 I guess I could send announcements to you to send out
20 to this mailing list.

21 SECRETARY SULEIMAN: Orhan Suleiman.
22 Well, they are open. I mean, I don't see why members

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1 couldn't participate. I wanted to clarify something,
2 Howard. A lot of the requirements that people are
3 concerned about, they are already part of the existing
4 standard.

5 We are really talking about upgrading the
6 warning label and upgrading an exposure schedule that
7 only deals with one skin type. So one of the
8 controversies that occurred at the workshop back in --
9 I think it was September, was some of the industry
10 people were really ignorant, and it was like we were
11 writing standards for the first time.

12 We have standards already on the books,
13 and we are just trying to upgrade them with the more
14 current science. And the meetings -- yes, when the
15 meetings are, send them to me, and we will send them
16 out and let members of the committee learn about them.

17 DR. CYR: All right.

18 MS. KAUFMAN: Excuse me, but was there
19 anything on -- I am trying to recall some years back,
20 but was there anything on trying to have more
21 consistency in the output of the bulbs, and the
22 information that was supplied to the manufacturers on

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1 assuring more uniformity between various bulbs? Was
2 there something on that?

3 DR. CYR: Very much so. That was not one
4 of the five, but since our presentation last year, the
5 industry itself had meetings with State regulators,
6 and found out that issues of lamp compatibility, and
7 had to exchange one lamp for another, is probably one
8 of their top most concerns.

9 And I think you will notice that at one of
10 the meetings that we had that I just said FDA-Industry
11 Workshop on Lamp Compatibility, and this is in the
12 planning stages. It was very much in the planning
13 stages.

14 When we are going to Chicago to this
15 meeting of the American Society for Photobiology, we
16 are going to meet with several people from industry.
17 They are participating in this conference in Chicago,
18 and we are going to meet after one of your sessions
19 and talk about when to have this meeting, and what
20 issues to bring up, and where to have it.

21 And we hope that this comes up pretty
22 soon, maybe as early as this fall, September or

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1 October of this year, to talk about those issues.

2 MS. KAUFMAN: I think that was the one
3 that mainly I was concerned about.

4 DR. CYR: Yes, this is a very important
5 concern, and it is being worked on very actively.
6 Sharon Miller in our engineering group is heading that
7 effort. She knows more about lamp compatibility
8 issues than I do, and she is not here right now, but
9 she will be the one that will be heading that
10 particular part of that effort here.

11 CHAIRMAN ROTHENBERG: Thank you. I just
12 wanted to clarify. You will try to maybe get us on
13 the announcement for those meetings?

14 DR. CYR: Definitely. I will try to get
15 you on the announcement for those meetings.

16 CHAIRMAN ROTHENBERG: Okay. Thank you
17 very much. Thank you again, Ms. Gill, also. The
18 next item is open public hearing. We have no one who
19 had requested to speak here but we do have a statement
20 from Tom Quinn, which was available to the committee,
21 and also on the table outside, and that statement will
22 be entered into the record for the meeting.

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1 Since we are somewhat earlier than
2 scheduled, possibly we will postpone the break to a
3 later time, and sort of in the middle of the session,
4 and would it be possible for Dr. Shope to give his
5 presentation now?

6 So Dr. Thomas Shope will speak on concerns
7 regarding radiation doses from filmless technologies.

8 DR. SHOPE: Good morning. My purpose for
9 my part of this discussion this morning is really to
10 introduce the topic and to lay some groundwork for the
11 following two presentations which will get into a
12 little more technical details.

13 What I hope to do is sort of pose the
14 issue and introduce it so that you will have an
15 opportunity to think about the issue while the
16 discussions are ongoing, and then following both
17 presentations have a period of discussion where we can
18 get your comments and opinions.

19 In conjunction with this issue of digital
20 imaging modalities, we really don't have a specific
21 regulatory proposal for the committee to review.
22 Rather, we are only at the stage of wanting to discuss

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1 with the committee some of our early thoughts and
2 possible approaches to dealing with this issue, and
3 the concerns that we have about it.

4 And technology willing here, we will have
5 a slid ein a moment. The projector takes a moment to
6 warm up, I guess. The first thing that I wanted to do
7 was just briefly discuss with the committee the role
8 of the committee, and this is also to some extent with
9 the audience here, as to the fundamental role of the
10 TEPRSSC committee, which is to provide the FDA and the
11 Commissioner with advice on proposed regulatory
12 standards.

13 And the other thing is to note that our
14 FDA responsibilities go somewhat beyond just
15 regulatory standards, and get into some areas where
16 the charter for the TEPRSSC committee is not really
17 specific, but as a group of experts whose opinions we
18 value, we would like to have an opportunity to discuss
19 some of the other possible approaches that we might
20 use in addition to regulatory approaches to deal with
21 this particular issue that we want to discuss.

22 (Brief Pause.)

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1 DR. SHOPE: I have highlighted here
2 briefly the charge of the TEPRSSC committee, and just
3 to emphasize that the charge for the committee is to
4 provide advice and consultation on performance
5 standards related to controlling the emission of
6 radiation from electronic products. The next slide.

7 The Act though gives the FDA some
8 additional responsibilities beyond just performance
9 standards. We are charged in the act with the ability
10 to be involved with the research, development, and
11 training, and operational activities related to public
12 health issues related to electronic product radiation;
13 to maintain liaison and receive information on present
14 and future electronic product radiation issues; to
15 study and evaluate the emissions and conditions of
16 exposure to electronic product radiation; and to
17 develop, and test, and evaluate procedures and
18 techniques for minimizing this exposure. And some of
19 these things are not really regulatory in nature.
20 Next.

21 In addition to these activities, the
22 Secretary, and in this case the Secretary of Health

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1 and Human Services, who was the person being described
2 in the Act, and that authority is delegated to FDA,
3 collects and makes available the results of research
4 and other studies related to electronic product
5 radiation.

6 And also is authorized to make
7 recommendations relating to these hazards in ways that
8 might be used to control them. Next slide.

9 So that is the general overview of our FDA
10 authorities and responsibilities regarding electronic
11 product radiation. In particular, the discussion for
12 this morning is of particular concern that we have
13 relating to digital x-ray imaging modalities.

14 And here I have described them as computed
15 tomography, digital radiography, and computer
16 radiography, and specific descriptions of these will
17 be presented by the next two speakers.

18 But the principal concern we have is the
19 sort of lack of a fundamental limitation that we see
20 with regular film screen imaging, which is too much
21 exposure results in black films, which is an optic
22 lesson for the person making the exposure not to use

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1 that much exposure the next time around.

2 But these digital modalities don't have
3 this fundamental limitation. Our concern is what will
4 be the long term impact of this on patient dose, and
5 are there some concerns here that the FDA ought to be
6 taking some action with regard to, and what actions
7 might be appropriate for FDA in this issue, both in
8 the regulatory or the non-regulatory area.

9 What is the magnitude of the problem that
10 we are concerned about? Well, unfortunately we don't
11 have any current comprehensive national nationwide
12 data on patient exposures from all these different
13 modalities.

14 It would be nice to have and in fact we
15 are in some discussions with some of the other
16 government agencies currently about how we might do a
17 better job of collecting this kind of comprehensive
18 national data. But that is a story that is still
19 unfolding

20 Our nationwide evaluation of x-ray trends
21 program, the next program that we operate in
22 conjunction with the conference of radiation control

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1 program directors, is really the only current
2 representative U.S. data on patient exposures, and
3 that is limited primarily to one examination per year,
4 and it cycles through a number of select examinations
5 that gives us some idea of the trends.

6 But it doesn't really address all of the
7 various examinations that are performed, particularly
8 the less frequently done examinations. Published
9 reports though indicate that patient doses from CT are
10 a significant portion the total medical exposure these
11 days that patients get from medical procedures.

12 And the other observation that one can
13 make is that CT doses are large compared to other
14 typical diagnostic exams, and we will talk in a little
15 more detail about that in a moment.

16 So there are some fairly good data about
17 CT available, and not so much from the U.S., but from
18 some other countries that probably have experience
19 very similar to what is happening here in the U.S.

20 Data for digital radiography and computed
21 radiography is kind of a mixed picture at this point
22 as to what the impact of these technologies are on the

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1 typical patient dose or the average patient dose.

2 Clearly these systems are capable of
3 delivering patient doses similar to conventional film
4 screen systems, keeping in mind that film screen
5 systems have a range of exposure capabilities, which
6 we refer to as the film screen speed indicator, and
7 depending on the detail needed in the imaging
8 procedure, various speeds of film screen systems can
9 be chosen, resulting in various levels of patient
10 exposure. Next.

11 Looking at this digital radiography and
12 computed radiography issue a little bit, we don't have
13 any large scale national surveys on patient doses from
14 these two modalities as of yet.

15 In fact, the current 2001 next survey we
16 hope -- and that is being designed with the intention
17 of capturing some information on chest examinations
18 performed with digital modalities. We are actually
19 trying to seed the sample selection here to make sure
20 that we do capture a significant number of digital
21 modalities doing chest examinations to get some idea
22 of what the impact on patient dose is from those types

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1 of equipment.

2 There is indications from the literature
3 looking at reports from various institutions that have
4 been published that computed radiography doses are
5 comparable to film screen doses, and typically
6 comparable to film screen systems having speeds of 200
7 or 400, in that range.

8 Clearly, CR systems, as Bob Gagne will
9 discuss later, can present higher doses, and I am not
10 sure if there is much opportunity to use lower doses,
11 although that certainly is capable from their dynamic
12 range to deal with lower doses and provide imaging
13 capabilities.

14 There are some reports either from
15 individual facilities or manufacturers that describe
16 the implementations of the various types of digital
17 radiography systems and these present somewhat of a
18 mixed fixture.

19 Typically, we see that there appears to be
20 a patient dose reduction possible from digital
21 radiography systems, but there is a lot of variability
22 and a lot of it depends here. It is clear task

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1 dependent on what exam is being performed and the type
2 of equipment being used.

3 And you will see that there is a variety
4 of equipment for this type of digital radiography
5 procedures. There are some concerns that we have
6 about certain implementations of digital radiography
7 that are fairly dose inefficient, and we want to make
8 sure that we keep an eye of those issues.

9 There are reports in the literature of
10 dose reductions from typical film screen systems when
11 you replace those by a digital radiography system, 25
12 to 50 percent dose reductions from the same clinical
13 task, giving the clinicians the imaging information
14 they require to do an adequate exam.

15 But these are not data from basically
16 nationwide kind of studies or region wide kind of
17 studies. They are more institutional experience,
18 particular exam experience in a particular
19 institution.

20 The other concern that we have is for
21 digital radiography and computed radiography, what
22 will be the long term stability of those levels. If

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1 a facility moves from film screen to one of these
2 digital modalities, and gets it set up according to
3 manufacturer's instructions and it is basically
4 performing equivalent to a 200 or 400 film screen
5 system, and the manufacturer now goes away, and it is
6 now the responsibility of the facility to keep the
7 system operating appropriately, what are the quality
8 assurance measures that are necessary to make sure
9 that the doses don't drift.

10 And the concern that I think we have is
11 drifting upward, as opposed to drifting downward here.
12 Downward would clearly, I think, result in some
13 adverse image quality issues with regard to noise, and
14 would probably be noticed.

15 But if the exposure drifts upward,
16 probably the noise in the images gets better and the
17 facility or the clinicians using the images won't
18 really notice adverse imaging quality.

19 But there is the potential for an
20 increased patient exposure when the wide dynamic
21 range, the ability to deal with an exposure that for
22 a film screen system would have resulted in a black

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1 film, and knowing that you are overexposing the
2 patient. Next slide.

3 Just to talk a minute about our knowledge
4 about CT, I picked up a couple of surveys basically to
5 here from the United Kingdom that shows the growing
6 use of CT and the experience in the United Kingdom.

7 This was a rather comprehensive survey
8 that has actually been done twice now in the U.K. In
9 1989, they looked at their nationwide experience in CT
10 and saw that CT was 2 percent of the radiological
11 examinations.

12 But in looking at the population dose
13 impact of that, saw that it contributed about 20
14 percent of the collective effective dose in the U.K.
15 And they have fairly good data in the U.K. for the
16 collective dose from the other radiological exams, the
17 non-CT exams, which in the U.S., we don't have quite
18 that handle on the situation currently.

19 In 1995, they did the same sort of study
20 again, and this is data from the National Radiologic
21 Protection Board, and CT was 4 percent of all the
22 exams, but it delivered at that point about 40 percent

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1 of the collective dose, showing a significant increase
2 in the dose coming from CT.

3 Similar data is available in a not quite
4 a comprehensive format from Germany, and it shows
5 about the same sort of thing. A recent paper here in
6 the U.S. just gives the experience from one facility,
7 the University of New Mexico, in Albuquerque, where
8 they did a look at what was going on in their
9 radiology department, and saw that currently CT was
10 about 11 percent of all the exams done.

11 But looking at their department's
12 experience, they thought that CT was delivering almost
13 70 percent of the dose to patients from radiologic
14 procedures in their facility.

15 I do not think this includes any nuclear
16 medicine does in the comparison, but I am not
17 absolutely sure of that. Next slide. Just to talk a
18 minute about what this collective dose business or
19 effective dose means.

20 I just wanted to remind folks that for a
21 long time we were using the quantity of the effective
22 dose equivalent, which came from an ICRP report, and

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1 recently we changed the terminology and the way of
2 calculating this by changing some of the factors, and
3 it is now effective dose.

4 But really this is a method for accounting
5 for the non-uniform irradiations that occur in
6 diagnostic radiology, using weighting factors and the
7 risks that occur to various organs, depending upon the
8 amount of radiation that an individual organ receives,
9 and the risk for cancer induction in that particular
10 organ from the radiation.

11 So it is really just a scheme for saying
12 what would be the comparable effect if instead of
13 getting this non-uniform exposure, what uniform whole
14 body exposure would produce the same risk. And so
15 that is what this effective dose means.

16 It is an equivalent comparison to just a
17 uniform whole body dose. Next slide. And just to
18 give you an example. This is from the United Kingdom
19 study back in '89, but in the first column there I
20 show the effective dose equivalent from computed
21 tomography and in the second column it is conventional
22 x-ray imaging.

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1 And it compares this equivalent dose or
2 effective dose equivalent for CT of the head, for
3 chest exams, compared to a chest film, and you notice
4 that we all I think know that a chest radiograph is a
5 rather low dose exposure.

6 And when you look at the effect of it on
7 the overall effective dose, a chest radiograph is
8 equivalent to .05 mSv whole body exposure. The
9 abdomen CT exam is 8.8 Msv. For those who have
10 trouble converting the numbers, 8 Msv is .8 rads, or
11 800 rads, I'm sorry. I am getting it backwards, too.

12 It is 800 millirads, or .8 rads, for the
13 pelvis; and for barium enemas, it is not a
14 conventional radiographic exposure, but it is a
15 fluoroscopic exposure that depends critically the
16 length of time the procedure goes on, and not just the
17 dose required to expose a given film, and often there
18 are multiple films.

19 But the point here of that number is to
20 show that the CT exams and some of the fluro exams are
21 comparable in dose, at least in the U.K. experience
22 about 10 or 12 years ago. Next slide.

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1 Just to show some recent numbers from
2 Germany, or at least more recent than the U.K.
3 numbers, a slightly different breakout, and here we
4 are using the newer effective dose numbers which came
5 about, and the weighting factors and the risk factors
6 are different based on the 1990 ICRP report.

7 And using those numbers, in Germany, we
8 see doses for a chest CT exam equivalent to about 2
9 rads, and almost 3 rads for the abdomen exam, or 27
10 Msv.

11 The average there is about one rad
12 equivalent whole body dose from a CT exam, and the
13 frequency of these exams in the German experience is
14 shown in the right-hand column. So, head exams are
15 still a large proportion, and they are the lower dose
16 type procedures. Next slide.

17 The concern in CT is sort of tried to be
18 highlighted in this slide. When you look only at the
19 volume of tissue that is actually imaged during a CT
20 scan, the actual radiation impinging on that tissue is
21 on the order of 10 to 50 Msv, or 1 to 5 rads, in a
22 typical CT procedure.

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1 There are clearly CT procedures and ways
2 of operating CT systems that give doses in excess of
3 5 rads to the tissue that is actually imaged. If you
4 then convert that dose to the tissue that is actually
5 imaged to the effective dose, which gives you the risk
6 comparison to a whole body exposure, the CT doses
7 range from 2 to 20 Msv, or comparable to a .2 to 2
8 rads whole body dose.

9 And the point of the slide is to note that
10 these doses from CT are now not requiring orders of
11 magnitude extrapolation from the data that we have,
12 say, from the incidents of cancer in the atomic bomb
13 survivors in Japan, who were exposed to doses only
14 slightly larger than this, and I think the lowest
15 range of doses that they have seen increases in cancer
16 incidents among the atomic bomb survivors is in the 5
17 to the 20 rad range.

18 And so from 2 rads in a CT exam, we are
19 not far from that. We are not talking about orders of
20 magnitude extrapolation. There is some controversy
21 about this data from the atomic bomb survivors, the 5
22 to 20 rads. There are papers that will argue that

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1 maybe they didn't really see cancer effects of those
2 doses, and it was more like a hundred rads.

3 But I think the message here is that there
4 is not a tremendous, several orders of magnitude,
5 extrapolation required here, and that is something
6 that we need to keep in mind when thinking about the
7 CT doses. Next slide.

8 So our concern about CT can sort of be
9 summed up in three areas. We are concerned about CT
10 techniques when children or small patients actually --
11 it could be small adults that were imaged. There was
12 some recent publications in the American Journal of
13 Roentgenology that raised this issue.

14 I don't think this surprises, and Stan
15 will talk a little bit about this. We also know that
16 with the modern CT systems they are scanning faster,
17 and that allows larger volumes of the patient's tissue
18 to be scanned, or to be imaged.

19 And there is a concern about the growing
20 use in some circles of CT use for screening either to
21 get your cardiac artery conditions screened or for
22 lung cancer detection that is being proposed, and

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1 discussed, and studied. And so we are a little -- we
2 want to keep our eye on this issue as well. Next
3 slide.

4 For digital radiography and computed
5 radiography that are the digital modes that are for
6 conventional imaging, we want to know more about what
7 the actual dose experience is, and actual use and
8 implementation of these systems.

9 What is the long term stability of the
10 dose levels from these, and is there a potential for
11 dose creep as you might describe it, and what actions
12 by FDA would contribute to the optimum use of these
13 imaging modalities, both from making sure the image
14 quality stays appropriate, and that the clinical tasks
15 are able to be done, and that the dose is kept under
16 control. Next slide.

17 That ends my introductory remarks, sort of
18 posing what the issues are here. The next
19 presentation will be by Dr. Stan Stern, who will
20 discuss CT. He will be followed by Dr. Robert Gagne,
21 who will discuss the digital radiography and computed
22 radiography issues a little bit.

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1 So whether you want to call a break now or
2 continue, I guess I will leave that to you. I don't
3 think there is a need for questions at this point, but
4 if people have them, I guess I could entertain them.

5 MS. KAUFMAN: Could I ask a question?

6 DR. SHOPE: Yes.

7 MS. KAUFMAN: Kathleen Kaufman. As I
8 looked at the other presentations, it appears that
9 they are not focusing on doses as much as your
10 presentation did. So my question is on dose. What
11 kind of doses are you seeing on the faster, newer CT
12 scanners?

13 DR. SHOPE: Well, I think the numbers here
14 reflect that.

15 MS. KAUFMAN: Do you think that they are
16 the same?

17 DR. SHOPE: I think they are similar.
18 There is nothing so inherent in the dose per volume
19 image with spiral scanners. Again, we are just
20 analyzing the data from the 2000 CT survey, which when
21 that data is analyzed, give us a better handle on
22 that.

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1 Clearly the percentage of facilities that
2 have spiral scanning, and the multi-slice scanning, is
3 growing. It is probably 80 percent of the CT systems
4 in the U.S. now are that way.

5 And I think for the German data that a
6 large number of those systems did have the multiple
7 slice or the spiral scanning capability. So we will
8 know shortly when we finish looking at the next data
9 what our real experience is.

10 I believe that the next protocol called
11 for using exactly the same measurement technique for
12 those units as it did for a more conventional CT
13 scanner.

14 And in my program, we actually measure the
15 dose using protocols on every CT scanner we inspect
16 every time we inspect them. And we were getting very
17 different values, lower values, for those spiral CT
18 scanners, and it caused me some concern relative to
19 the measurement protocol.

20 That maybe there is something different in
21 those scanners that our instruments aren't picking up
22 all of the dose, or --

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1 DR. SHOPE: Well, clearly, doing dose
2 assessment for the spiral scannings requires a little
3 bit of care in how that is done. There is nothing
4 inherent in a spiral scanning mode that implies that
5 the doses are going to be dramatically different,
6 except the implication of the pitch.

7 You know, how fast does the patient move
8 through it, and if the patients move through it so
9 that the pitch is much greater than one, obviously the
10 doses are going to be reduced. But you are going to
11 be probably having noiser images.

12 So I think we are in the process of trying
13 to sort that out with some of the activities that are
14 ongoing with the IEC standard for CT that will be
15 touched on briefly in the following presentations.

16 CHAIRMAN ROTHENBERG: I think I would just
17 comment from my experience in looking at some of these
18 machines that in general the doses are not higher with
19 the spiral scanners, and in some cases they are
20 somewhat lower.

21 But in general one of the concerns is what
22 you mentioned, is covering larger volumes of the

1 patients. So more tissue would be eradicated, but the
2 dose to the eradicated tissue was similar.

3 Also, some of the screening techniques
4 employ lower techniques, and so I think maybe Dr.
5 Stern will be covering some of that.

6 DR. SHOPE: The point about even if you
7 are using sort of the same dose per scan, but by
8 scanning more tissue that raises the effective dose,
9 because there are more organs being exposed, and that
10 risk gets factored into the effective dose
11 calculation.

12 DR. NELSON: I was wondering if you could
13 give us a comparison between the doses of a helical CT
14 for screening for pulmonary embolisms compared to the
15 VQ scans as a real movement towards going to CT scan
16 instead of VQ scans, and if there is a safety
17 difference, that would be very useful to know.

18 DR. SHOPE: I don't think we have any real
19 firsthand experience on that. I think typically in
20 the screening modes that people encourage the reduced
21 MA during those scannings. So that of itself would
22 reduce the dose because the lungs are less

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1 attenuating, and you can get a comparable noise image
2 with less MA.

3 So if facilities are doing that, the doses
4 from the lung screening kind of procedures would be
5 lower than the usual CT protocols would result. But
6 I don't think we have a lot of specific data in hand.

7 We could take a look at that and try to
8 look at that in more detail, but I think the amount of
9 lung screening is small now, but there is a potential
10 for it to grow as the clinical community learns how
11 best to use that modality.

12 CHAIRMAN ROTHENBERG: The two protocols
13 that I have seen in institutions in New York have
14 significantly lower MA, and I would estimate typical
15 doses on the order of maybe 2/10s of a rad, or 2 Msv.

16 SECRETARY SULEIMAN: I would like to
17 clarify something. Dr. Stan Sterns' presentation is
18 going to go into a little bit more detail. I think
19 you are absolutely right that there are a lot of
20 changes that have happened with CT.

21 I think I can competently say that we are
22 on top of them. I think that some of the questions

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1 are really challenges. We have not figured out how to
2 answer them.

3 I think some of the innovative things are
4 making patient follow through much easier, and so you
5 are seeing more patients undergoing exams. The dose
6 is probably per helical scanner, I suspect, maybe
7 lower, but there is some other things that the
8 manufacturers have done regarding the equipment.

9 Again, Stan will probably go into more
10 detail, but that have actually dose implications. So
11 those are going to be covered in the subsequent areas.
12 The other aside, Stan is pretty modest and he doesn't
13 want to say this, but another task that he is involved
14 with this year is he is developing an organ dose
15 handbook that will basically be aimed at the user
16 community.

17 And which will allow you to calculate the
18 dose from CT and come up with the normalized,
19 homogenized merit of effective dose. So you can
20 compare the doses.

21 It is not a trivial task, but he is using
22 some of the British data, and some of the next CT data

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1 that we collected last year, and so that is going to
2 be a tool that is going to allow us to answer some of
3 these other questions regarding what are the doses
4 from the pulmonary CT scan, and how does that compare
5 with a chest radiograph, and so on.

6 We don't have those answers definitively,
7 and you probably can get different opinions on what
8 the right answer is, but I think we are going to solve
9 that in the next year or two.

10 DR. MARX: Dr. Shope, do you have any data
11 in those slides that you have shown with the increased
12 volume Cts, and increased percentage of dose, and how
13 many actual people are getting more than one within a
14 relatively short amount of time, or is it just by a CT
15 scan?

16 Because a large -- you know, if you look
17 in any hospital, people have multiple, multiple
18 studies.

19 DR. SHOPE: I would -- we have not looked
20 at that in any great detail. The study from the
21 University of New Mexico that Dr. Mettler and
22 colleagues did, did look at that issue of how many

1 people have multiple CT procedures, and the number of
2 people having second, third, and fourth CT scans all
3 in one episode was not insignificant in my opinion.

4 And so I think there is a concern there.
5 It is not just that a patient gets this one time, but
6 many patients -- and I don't remember the exact
7 percentages, but we can find that in the article. As
8 I recall, it was something like five percent of the
9 patients they looked at had had four or more CT
10 procedures.

11 That is really off the top of my head, and
12 I could be off a little bit on that. But it was a
13 decreasing trend as you went from one procedure to
14 two, to three, to four.

15 So the numbers of patients having that
16 multiple procedures went down. But it was still a
17 significant number still having four or more
18 procedures.

19 DR. MARX: Now, one other point that I
20 just wanted to clarify is that the study that you
21 referred to with the CT pulmonary angiogram is
22 actually a very different study than a screening CT

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1 looking for lung cancer in completely asymptomatic
2 patients. So that is a little bit of apples and
3 oranges.

4 DR. NELSON: And that is --

5 DR. SHOPE: As opposed to --

6 DR. MARX: So there you would not be using
7 your low dose study, but you also have to factor in
8 the higher likelihood that you are actually going to
9 make a diagnosis over the --

10 DR. NELSON: Right.

11 DR. CARDELLA: I just wanted to make a
12 comment just for those that might not be familiar with
13 the phenomenon that is occurring, and that is in
14 regard to the use of CT scan as a screening tool.

15 By and large whether you believe that is
16 a good thing or a bad thing, the observation is that
17 it is outside of the factors that traditionally
18 regulate the use of examinations.

19 Screening Cts, the way that they are
20 marketed in many markets around the United States is
21 that the patient is self-paying for this, and it is as
22 though they would go in for it as you would go in to

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1 have your teeth cleaned to see are my lungs free of
2 cancer, and is my abdomen free of cancer, and the
3 payment is from the patient's own pocket.

4 So there is not an insurance payer
5 oversight of the process, nor is there typically a
6 referring doctor oversight of it. These patients
7 typically will present themselves for screening to in
8 many cases entrepreneurial groups that have set up
9 screening programs for the purpose of revenue
10 production basically.

11 So when you talk about screening as Dr.
12 Shope was talking about, it is not like screening
13 mammography, where there are some checks and balances.
14 It is an open free for all in many communities.

15 DR. RICE: I have a point of
16 clarification. If you are looking for pulmonary
17 emboli, a chest CT is a diagnostic tool, and not a
18 screening tool. No more than VQ scans for pulmonary
19 emboli. And in the clinical setting, it is a
20 diagnostic tool, and it is not a screening modality.

21 DR. NELSON: My point is that it is
22 unclear which is preferred; the VQ scan, versus a

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1 helical CT. And if we were to find that the radiation
2 dose for a helical CT is much greater than the VQ
3 scan, that might push clinicians to prefer the VQ scan
4 over the helical CT, or vice versa.

5 And if the helical CT has less radiation
6 exposure, we might start preferring that. Right now
7 it is up in the air which is the preferred procedure.

8 CHAIRMAN ROTHENBERG: Okay. I think maybe
9 we are now approaching our originally scheduled break
10 time. So rather than move on to the next talk, why
11 don't we talk about a 15 minute break, and we will
12 proceed then at about 5 after 10:00. Thank you, Dr.
13 Shope.

14 (Whereupon, the meeting was recessed at
15 9:50 a.m., and was resumed at 10:17 a.m.)

16 CHAIRMAN ROTHENBERG: Okay. We are going
17 to start and with regard to the morning schedule, we
18 are going to try and finish up the items on the agenda
19 for the morning, and have lunch at noon, as opposed to
20 1:00 p.m., and see if we can move everything forward
21 a bit.

22 Our next speaker is Dr. Stanley Stern, who

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1 is going to speak to us about issues related to
2 computer tomography.

3 DR. STERN: Thank you very much. My talk
4 is going to be in the framework of standardization and
5 regulation with regard to the CT asymmetry. Can I
6 have the next slide, please.

7 The purpose of this presentation is to
8 brief you and elicit any comments about FDA activities
9 and its current thinking concerning recent
10 developments in x-ray computed tomography.

11 The themes running through this
12 presentation are grouped into four categories. They
13 are radiological practice, rapid technological change,
14 revision of industry standards and development of
15 guidance and regulation.

16 The most recent reminder of the potential
17 impact of CT conduct is a practice that may expose
18 pediatric patients to an excess risk of cancer from a
19 larger than needed radiation dose.

20 And I will discuss this situation in
21 somewhat more detail in the next slide. Another
22 example of radiological practice affecting dose is the

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1 small, but growing, frequency of profusion or contrast
2 phase studies involving a mode often referred to as CT
3 fluoroscopy.

4 The common denominator for many of these
5 interventional applications is the repetitive
6 irradiation of one level of the patient's body as the
7 x-ray tube rotates many times at a more or less fixed
8 axial position.

9 Fixed position repeated rotation studies
10 raise the important question of how a new dosimetry
11 standard might quantitatively account for doses
12 incurred in interventional modalities. How does one
13 evaluate dose and in what precisely defined terms.

14 Examples of rapid technological changing
15 include multi-slice helical scanning and adaptive
16 current modulation. Multi-slice helical CT is here
17 and now. It represents a major advance in single
18 breath hold imaging, which facilitates visualization
19 of small lung nodules.

20 It enables angiography, fast volume metric
21 scanning, a three dimensional rendering. However, for
22 some scanner models, multi-slice helical CT also

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1 brings with it a geometrically inefficient use of
2 radiation. I will talk briefly about that issue in
3 one of the following slides.

4 Adaptive x-ray tube current modulation
5 refers to the capability of a CT unit to reduce or
6 increase the x-ray tube current dynamically as the
7 tube rotates around the patient in order to yield the
8 least amount of radiation necessary for visualization.

9 It changes the current on the fly to
10 accommodate the patient thickness attenuating the x-
11 ray beam, and it offers the prospect of an automated
12 way of obtaining an optimal radiation dose.

13 One key take home message is that the
14 repetitively of change in CT practice and technology
15 has left the field so unsettled that not even the
16 nomenclature is standardized.

17 This point is particularly important with
18 respect to recent attempts to revise a new
19 international safety standard for CT equipment so as
20 to have scanners display an index of radiation dose.

21 There are two aspects of standardization
22 that are intimately related to how dose and associated

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1 parameters ought to be defined. The first aspect is
2 a European initiative to have clinical facilities
3 apply what are called reference levels in their
4 quality assurance programs.

5 In the United States, there is a similar
6 move underway by the American College of Radiology
7 through a test group of the American Association of
8 Physicists in Medicine to introduce what are called
9 reference values into general use by facilities.

10 The second aspect of standardization is
11 the potential role of the FDA in requiring new
12 performance standards for CT equipment. I will
13 briefly discuss both aspects. Can I have the next
14 slide, please.

15 Recently, there has been publicity about
16 CT exams of pediatric patients subject to excessive
17 radiation dose and to the associated risk of premature
18 cancer modality over the course of their lives.

19 The publicity stems from four related
20 papers in last February's issue of the American
21 Journal of Roentgenology. Their publication comprises
22 a valuable service for public health because it

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1 informs the radiology community about a serious
2 problem that it can solve.

3 Here are the two principal messages that
4 these papers overrule. First, when examining
5 pediatric patients, many facilities do not readjust CT
6 scanner parameters after having previously examined
7 adults.

8 No readjustment means that smaller,
9 thinner patients probably receive more radiation than
10 is needed for visualization. Second, there is a
11 practical solution.

12 If facilities reduce the x-ray tube
13 current according to the patient weight, the dose can
14 be cut substantially with no loss of clinical
15 efficacy.

16 In this group of papers the perspective by
17 Donnelly and Colleagues even provides a technique
18 chart to guide to current reduction. So in the view
19 of CDRH, the problem is one of appropriate use of
20 equipment, and the quickest way of dealing with it is
21 to get this message out to the user community.

22 The American College of Radiology

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1 published this issue in its February bulletin to
2 radiologists, and that article also mentions their
3 development of a CT facility accreditation program,
4 with a particular component for pediatric patients.

5 The American College of Radiology
6 accreditation program has been two years in the
7 making, and it is in the final stages of testing, and
8 it will evaluate the ability of a practice to use the
9 minimum amount of radiation needed to produce high
10 quality CT images.

11 Furthermore, the current American College
12 of Radiology standard for a thoracic CT have specific
13 recommendations for reducing dose to pediatric
14 patients, such as increase the table increment or
15 pitch, or lower the tube current, and use partial
16 scans if appropriate and shorten scan times.

17 I have emphasized pitch with bold typed
18 face to underscore its importance in the context of
19 standardization of nomenclature. The way that the ACR
20 standard uses the pitch is a good example of the
21 prevalent understanding of how this particular scanner
22 setting may be increased in order to reduce dose, and

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1 I will talk about that more later.

2 One significant contribution of CDRH has
3 made in this area has been through the nationwide
4 evaluation of x-ray trends program in collaboration
5 with the Conference of Radiation Control Program
6 Directors.

7 We have just completed a survey of
8 computed tomography facilities in the United States,
9 and we posed the question of whether dedicated
10 techniques were used for pediatric patients. 43
11 percent of the facilities responded yes.

12 The CT survey is based on a nationally
13 representative random sample of facilities, and this
14 particular information about the prevalence of
15 dedicated pediatric technique represents the first
16 quantitative datum on the true magnitude of the
17 problem.

18 The mortality projection published in the
19 American Journal of Roentgenology was based on an
20 assumption that facilities generally did not use
21 pediatric technique, and now we know that that
22 particular assumption is not true, and that its

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1 modality projection therefore is overestimated.

2 Nevertheless, it is worth emphasizing that
3 the underlying points of that study are valid and
4 important. Cancer mortality risk associated with
5 radiation dose is higher in children than adults.

6 Dose can be reduced in pediatric CT, and
7 there is a long way to go in getting all facilities to
8 use appropriate techniques with pediatric patients.
9 The FDA might consider distributing a safety
10 notification about the potential for larger than
11 needed dose in some pediatric CT practice.

12 Such information would make people aware
13 of the problem, and it would inform them about
14 appropriate CT technique for pediatric patients. We
15 solicit your input on whether to issue a formal
16 notice, and if so, what particular information it
17 might provide.

18 If the FDA were to take such a step, we
19 would want to be very mindful of conveying a complete
20 context concerning pediatric Cts, and of underscoring
21 its diagnostic efficacy so as to not to dissuade
22 parents from providing their children with examination

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1 benefits that generally overwhelmingly outweigh
2 individual risk. The next slide, please.

3 A central issue in managing patient
4 radiation dose and computed tomography is that of
5 defining a good representation of dose with respect to
6 the radiation emitted by any particular CT system
7 during a procedure.

8 When one thinks of patient dose, the first
9 thought that comes to mind is that of effective dose.
10 Effective dose is a radiological variable frequently
11 used in occupational health and medical physics, and
12 it is a whole body dose equivalent of cancer risk
13 associated with radiation detriment.

14 However, because effective dose is tissue
15 based, it is practically impossible to measure. So
16 for CT, a good representation of patient dose is a
17 quantity that is first easily measurable for any
18 particular CT scanner in the absence of a patient.

19 And, second, that nevertheless corresponds
20 reasonably well to the magnitude of energy absorbed by
21 real tissue. And, third, at the same time reflects
22 examination characteristics, such as duration, spatial

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1 extent, and ideally anatomical locations irradiated.

2 At the core of the issue of dose
3 representation is how technology and practice have
4 progressed beyond the applicability of dose indices
5 and terminology defined 20 years ago with the adoption
6 of the current U.S. mandatory standard for CT
7 equipment performance.

8 Here are the key features of the current
9 U.S. standard with respect to those. The most
10 important aspect is that dose information must be
11 provided as documentation by manufacturers to users.

12 There is no requirement for a real time
13 display of radiation output. There is no regulatory
14 limit to the dose. There is no limitation on how
15 efficiently the x-ray field may overlap the active
16 detector area used to form images.

17 And there is no requirement for the
18 provision of any so-called automatic exposure control
19 systems. Such a system would be analogous to that
20 used in conventional radiography or fluoroscopy.

21 It would optimize the amount of radiation
22 needed for visualization to minimize dose according to

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1 the physical girth of a patient attenuating the x-rays
2 sensed by the detectors.

3 To sum up the only requirement is that
4 manufacturers document typical values of dose. There
5 are no standards requiring physical limitations to the
6 dose or to the extent of the x-ray field.

7 A dose is characterized by specially
8 defined quantity called the computed tomography dose
9 index, abbreviated CTDI, and because this index figure
10 centrally represents dose and computed tomography, I
11 would like to take a minute to describe CTDI, and to
12 point out some of its features and its limitations.
13 Can I have the next slide, please.

14 The overarching limitation is that CTDI is
15 defined only for axial scanning. The second figure
16 depicts what happens in a single axial scan.
17 Typically the X-ray source rotates around the patient,
18 and the figure shows a cylindrical phantom, with no
19 axial movement of the patient's support table.

20 The beam is culminated narrowly in the
21 axial direction, where single image slice can have a
22 fitness T ranging from one to approximately 10

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1 millimeters.

2 In a tomographic plane depicted on the
3 left as the phantom face, the beam is fan shaped and
4 broad enough to cover the cross-section being imaged.
5 An essential physical aspect of this irradiation
6 geometry is that even though the x-ray field is
7 tightly collimated the axis, once the field begins to
8 penetrate a patient or a phantom, the radiation
9 scatters a great deal, and its axial extent broadens
10 significantly.

11 The graph on the right shows this
12 broadening in what is called a dose profile. The
13 lower part of the graph represents a single axial scan
14 dose on the ordinate as a function of the axial
15 position on the abscissa.

16 The profile shows how the dose varies.
17 For example, between points A and B, and the central
18 peak corresponds mostly to the primary beam passing
19 through the collimator.

20 Although the system is collimated to
21 obtain a tomographic section of thickness of 13
22 millimeters in this example, in fact the dose extends

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1 far beyond the 13 millimeter width, to more than a
2 hundred millimeters on either side of the peak.

3 To represent this phenomenon of
4 distributed dose as a single parameter, CTDI is
5 measured for a single axial scan in an acrylic
6 phantom, and it is defined in terms of an integral of
7 the dose profile over a range that is intended to
8 include most of the scattered radiation contributions,
9 as well the primary radiation.

10 This range extends over a distance equal
11 to 14 slice widths, from minus 7T to plus 7T. For
12 slices of thickness greater than 7 millimeters, which
13 was typical of axial scanning 20 years ago, the
14 integral includes most of the area under the curve,
15 and is a reasonably good representation of dose.

16 The parameter "n" in the definition of
17 CTDI is the number of tomographic images obtained in
18 a single scan, and these days "n" typically is 1, 2,
19 or 4. When more than one tomogram is produced in a
20 single rotation, the collimation is widened to
21 accommodate a total scan width corresponding to the
22 product n times T.

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1 One can show that CTDI is really a
2 particular kind of procedure dose. In axial scanning,
3 usually one does multiple scans covering a clinical
4 region of interest along the z axis.

5 If these multiple scans are contiguously
6 spaced by an increment "I" that is equal to the scan
7 width Nt , then the dose contributions from the tails
8 of adjacent profiles add up as depicted by the broad
9 dashed curve in the upper part of the graph on the
10 right.

11 For such a procedure, CTDU is equivalent
12 to the average dose in the central portion of a series
13 of 14 contiguous scans. There can be other kinds of
14 procedures involving multiple axial scans. For
15 example, the increment "I" between scans may be twice
16 the scan width.

17 In that case the multiple scans are not
18 contiguous. They are spaced apart from one another,
19 and the average dose in the center of a series would
20 be reduced. There can also be procedures where the
21 scans are spaced more closely to one another.

22 In other words, they overlap. An index

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1 called the multiple scan average dose, abbreviated
2 MSAD, represents the average dose in the central
3 portion of a series of multiple scans, whether the
4 scans are contiguous or not.

5 And MSAD reflects the dose associated with
6 the scan spacing of the procedure. The equation on
7 the right shows the relationship between the multiple
8 scan average dose and CTDI. When the scan increment
9 "I" equals Nt , this ratio -- well, that ratio, that
10 denominator, is one, and CTDI is equal to MSAD in that
11 case. Next slide, please.

12 Starting around 1990, CT systems capable
13 of helical scanning were introduced into the market,
14 and since then they have increased in popularity so
15 much that today more than 80 percent of the most
16 frequently used CT scanners in facilities can do
17 helical scanning.

18 The figure in this slide depicts a helical
19 scanning movement. The patient support table moves
20 along the z axis at the same time that the x-ray tube
21 rotates, and the x-ray field traces out a helical
22 pattern around the surface of a patient or phantom.

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1 The message here is that there are no U.S.
2 mandatory performance standards or definitions
3 dedicated specially to helical CT. The U.S. standards
4 in place pertain to axial scanning CT. When
5 manufacturers and users of CT systems measure CTDI or
6 dose profiles, they operate their state-of-the-art
7 helical scanners in an axial scanning mode.

8 This particular practice is bothersome
9 because one expects that the dose profile for a single
10 rotation in a helical scanning mode to be broader than
11 that for an axial scanning mode.

12 And with no special Federal requirements
13 to represent helical dose, there may be some dose
14 information missing for the CT user. While the
15 absence of a formal definition of a dose index for
16 helical scanning tends to undermine the legitimacy of
17 CTDI characterizing dose associated with helical
18 systems, there are on the other hand empirical studies
19 showing first that CTDI measured during helical
20 scanning has approximately the same value as CTDI
21 measured during axial scanning.

22 And, second, that the helical scanning

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1 analog of MSAD can be approximated by CTDI, divided by
2 the pitch. In summary, the accurate representation of
3 a CT dose for helical scanning is ambiguous. For
4 helical scanning, pitch is an important parameter
5 corresponding to how tightly the helix is wound.

6 With the advent of multi-slice helical
7 scanning, the definition of pitch has become a point
8 of contention between some medical physicists and
9 manufacturers, whose respective interests are dose
10 characterization and management on the one hand, and
11 promotion of multiple image capability on the other.

12 The traditionally accepted definition of
13 pitch is the ratio of table travel, Δz , per
14 rotation, to the total slice width, Nt , per rotation.
15 And this definition was reflected in the first edition
16 of the voluntary CT safety standard adopted in 1999 by
17 the International Electrotechnical Commission.

18 According to this definition, when the
19 value of the pitch equals one, the slice widths of the
20 helix are contiguously spaced. For a pitch greater
21 than one the helix is spread out as depicted in this
22 slide, and the dose is reduced.

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1 And for a pitch less than one the slice
2 widths of the helix overlap one another. So with this
3 definition, pitch can be used as a factor to manage
4 dose, and as indicated by the relationship between
5 helical MSAD and CTDI, one can reduce MSAD by
6 increasing the pitch.

7 As I mentioned earlier, the current
8 voluntary standard of the American College of
9 Radiology for adult and pediatric computer tomography
10 uses pitch precisely this way as one means to control
11 dose.

12 Just two years after the first edition,
13 the IEC has recently adopted a second edition of the
14 CT standard containing a new definition of pitch,
15 which may be undergoing further revision at this time.

16 The new definition refers to only a single
17 tomographic section width T in what may be a multi-
18 tomogram helical scanning mode. This new definition
19 alters an accepted and conceptually accessible
20 representation of the overlap of the image tissue
21 volume, and it may lead to a long period of confusion
22 in the use of pitch for the quantitative estimation of

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1 dose.

2 Such ambiguity is a prime example of what
3 may ensue in the absence of precise definitions in a
4 U.S. standard. Next slide, please.

5 Since the introduction of CTDI 20 years
6 ago, there has been a proliferation of indices to
7 characterize different aspects of radiation dose and
8 computed tomography -- CTDI 100, and CTDI 100 central
9 or peripheral, weighted CTDI 100, and normalized CTDI
10 W, dose-length product.

11 Without getting into the details, I would
12 like to make three points, I would like to make three
13 points about the parameter proliferation. First, the
14 circumstance that there are so many parameters and
15 that many have ambiguous definitions, reflects how
16 rapidly the technology and clinical practice of
17 computed tomography has changed.

18 The nomenclature itself has yet to be
19 standardized. The medical physics and radiology
20 communities have not even settled on the terminology,
21 the words that define dose concepts changing to
22 accommodate technological innovation.

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1 The second point is that the core of each
2 of these indices is really comprised of a single
3 common parameter designed CTDI 100, and it is
4 highlighted in the red box. It does not show up so
5 clearly on this slide.

6 CTDI 100 is like CTDI with two significant
7 exceptions. One, the dose profile is integrated over
8 a fixed length, 100 millimeters, used in a
9 commercially available ionization chamber.

10 And, two, the reference medium for dose is
11 air, the air of the ionization chamber, and not the
12 acrylic material of the phantom that holds the
13 ionization chamber.

14 CTDI 100 has several advantages over the
15 FDA quantity CTDI as a dose index. First, for
16 tomographic sections of thickness less than 7
17 millimeters, which is more common for scanning now
18 than it was 20 years ago, the limits of integration
19 bounding CTDI 100 include more of the scattered
20 radiation contributions from the dose profile than
21 does a traditional FDA index CTDI, which is integrated
22 from minus 7T to plus 7T.

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1 There is a relatively larger scattered
2 radiation contribution the thinner the tomographics
3 section, and by including such contributions, CTDI 100
4 would tend to more accurately represent the dose for
5 thin section configurations than CTDI, which would
6 tend to underestimate the dose.

7 Second, fixing the limits of integration
8 also makes CTDI 100 much easier to measure with a
9 fixed length ionization chamber than CTDI because the
10 range of integration determining CTDI varies with
11 section thickness T.

12 Finally, the dosimetric reference medium,
13 air, of CTDI 100 is less energy dependent and more
14 representative of the x-ray energy absorption
15 coefficient in soft tissue than is polymethyl
16 methacrylate, PMMA, which is the dosimetric reference
17 medium, as well as the radiation-scattering matrix
18 defining CTDI.

19 The third major point of this slide is
20 that some of these indices may be better than others
21 as indicators of radiation risk associated with
22 patient dose.

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1 For example, CTDI 100 corresponds to a
2 measure of central slice dose at a specified location
3 in the phantom for one particular procedure, namely
4 multiply contiguous axial scans.

5 CTDI W is a little more general than CTDI
6 100 because it corresponds to the central slice dose
7 averaged over the entire tomographic cross-sectional
8 area, but still for the same particular kind of
9 multiply contiguous axial scanning.

10 Dose-length product, DLP, is even more
11 general, because it includes a measure of the entire
12 scanned region that the other parameters lack. A
13 patient receiving a combined chest and abdomen
14 examination incurs a greater risk than one who has a
15 chest exam alone simply because of the larger volume
16 irradiated in the first case.

17 While CTDI W would have the same value for
18 these two cases, the dose length product would be
19 larger for the combined chest and abdomen exam than
20 for just the chest exam, and therefore the dose length
21 product would better indicate the risk than would CTDI
22 W.

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1 The bottom line is that when we define
2 dose indices, we should be guided by their intended
3 use. Next slide, please. This slide highlights a
4 dose problem associated with the development of some
5 models of CT systems capable of multi-slice scanning.

6 The problem has to do with how efficiently
7 the radiation emitted is actually used to produce
8 clinically useful images, versus how much of it is
9 absorbed by the patient without contributing to the
10 image.

11 This phenomenon has been characterized as
12 over-beaming by Hans Nagel, and it is a good example
13 of how technological progress may carry challenges as
14 well as rewards.

15 The figures schematically depict a
16 comparison of the dose profile for a single-slice
17 system versus that for a multi-slice system. In both
18 figures, the length of the active detector along the
19 z axis, the axis of rotation, is shaded green, and
20 both figures portray the same overall width of the
21 tomographic section visualized, 4 millimeters in this
22 example.

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1 The difference between them is how that 4
2 millimeter section is produced. The figure on the
3 left corresponds to a single slice system, and the x-
4 ray detector is a single unit whose active length is
5 wide enough to subtend practically the entire axial
6 distribution of the radiation that has been
7 transmitted through the patient.

8 This distribution is just like the dose
9 profile that I showed on a previous slide. Here it is
10 represented by shades of gray, as well as by the
11 heights of the rectangles. The central black area,
12 the umbra, for the most part contains the primary
13 radiation that has passed first through the pre-
14 patient collimator, and then the patient.

15 On each side of the umbra are lighter gray
16 areas comprising the penumbra and radiation that has
17 been scattered from its initial direction by passing
18 through the patient.

19 All of this axially distributed radiation
20 is sensed by the detector, and I am talking about the
21 single slice case. And the detector signal is sent to
22 the computer as part of the process of image

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1 construction.

2 The full-width at half-maximum intensity,
3 which is denoted FWHM, of 4 millimeters, is determined
4 for the most part by how wide the pre-patient
5 collimator is open.

6 The figure on the right represents a
7 multi-slice system. In this example, there are four
8 independent x-ray detectors, each corresponding to a
9 width of one millimeter along the z axis.

10 Depending on how the radiologist wishes to
11 visualize the region of clinical interest, the signals
12 from each of the four detectors may be kept separate
13 to form four separate images, each one millimeter
14 wide, or they may be summed 2 by 2 to yield two
15 separate images, each 2 millimeters wide.

16 Or all four may be summed to yield one
17 single 4 millimeter wide image. In any case the width
18 overall of the tomographic section or sections
19 visualized is 4 millimeters.

20 And it is determined not by the pre-
21 patient collimator, but by the physical dimensions of
22 the detectors themselves. In order for each detector

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1 to separately sense an evenly distributed amount of
2 radiation, some CT models have the pre-patient
3 collimator open wider than 4 millimeters.

4 Wide enough to ensure that each detector
5 lies in the umbra of the radiation field, with none in
6 the penumbra. Such a system produces overall an axial
7 distribution of radiation that may be significantly
8 broader than 4 millimeters, 6 millimeters in this
9 example.

10 And this penumbra radiation is absorbed by
11 the patient without being used to form the image. Not
12 all multi-slice CT systems operate this way. But
13 their prevalence is an open question, and so is the
14 necessity of desirability for any system to operate
15 with this kind of inefficiency.

16 Is there a sufficient diagnostic advantage
17 for such multi-slice systems? Is the patient being
18 exposed to unnecessary radiation? We don't know.
19 Next slide, please.

20 I have just given an overview of
21 radiation-dosimetry issues in computed tomography, and
22 now I would like to outline current FDA activities

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1 related to CT.

2 Data acquisition for the CT survey of the
3 Nationwide Evaluation of X-rays trends has just ended,
4 and we are reviewing returns for entry into a database
5 which we expect to complete by September.

6 Last year before this Committee, I spoke
7 at length about the objectives and design of the CT
8 survey. Preliminary results offer a tantalizing
9 preview of the valuable information that we will gain
10 about CT dose in the United States.

11 For example, the multi-scan average dose
12 for head exams increased from 46 mGy in 1990 to 54 Mgy
13 in the year 2000, a change of ore than 15 percent.
14 This result and others exemplify how advances in CT
15 scanner technology may contribute to increased
16 collective dose, as well as to improved diagnostic or
17 interventional efficacy.

18 CDRH has been active in developing
19 consensus standards and guidance at an international
20 level. There are CDRH representatives to the
21 International Electrotechnical Commission maintenance
22 team responsible for the IEC safety standard for CT

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1 equipment, to the IEC working group developing an
2 acceptance test standard for CT systems, and to a task
3 group of the American Association of Physicists in
4 Medicine that is developing recommendations for the
5 American College of Radiology about reference values
6 for diagnostic x-ray exams.

7 The use of reference values or reference
8 levels would constitute a progressive move in an
9 facility quality assurance program of radiation
10 protection. These values correspond to the 75th
11 percentile of the distribution of dose as measured for
12 a particular radiological procedure.

13 Reference values are norms or benchmarks,
14 to which a facilities practice may be compared. When
15 the reference level is exceeded in any particular
16 examination, the facility may investigate to see if it
17 is possible to reduce exposure without adversely
18 affecting image quality.

19 So although we critically reviewed the IEC
20 CT standard, and believe that it needs significant
21 clarification and revision, its requirement for
22 display of dose indices represents a major step

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1 forward, because displays would be an essential tool
2 for evaluation of patient dose.

3 Knowing the dose is the starting point for
4 implementing a reference value program. We are
5 developing as Orhan mentioned, and I guess I am not so
6 modest, but we are developing a Handbook of Patient CT
7 Doses from CT Examinations for medical physicists and
8 radiologists.

9 It will be a compendium of doses to
10 radiation sensitive tissues for approximately 50
11 different CT examinations, and it is designed to be
12 generally applicable for any particular scanner model.

13 This handbook is expected to help facility
14 quality assurance programs, and it will facilitate
15 risk communication between clinical staff and
16 patients.

17 There is a research effort underway to
18 develop definitions and quantitative understanding of
19 the relationship between dose profiles, dose indices,
20 pitch, and related parameters for helical CT.

21 We expect to report preliminary results of
22 this work at the next annual meeting of the

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1 Radiological Society of North America. Finally, the
2 CDRH Office of Compliance continues its oversight with
3 reviews of CT product reports submitted by
4 manufacturers.

5 For CT, the Office has been focusing
6 recently primarily on issues that may be of pressing
7 concern. For example, the potential problem of
8 overbeaming that I alluded to earlier. Next slide,
9 please.

10 We believe that many of the concerns
11 related to technological and clinical developments in
12 computed tomographic exposure and dosimetry might be
13 best addressed through a two-tiered regulatory
14 approach; a policy decision that can be implemented in
15 the near term, and mandatory regulations that might go
16 into effect over a longer period.

17 It should be emphasized that the idea for
18 a regulatory approach is being introduced now for the
19 purpose of public discussion. It is just an idea, and
20 not an announcement of definitive or irrevocable
21 intent, and it represents FDA's current thinking of
22 possibilities only.

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1 No decisions have been made to implement
2 either a new policy or to propose new rules. In the
3 short term, we are considering the development of
4 guidance for manufacturers that would support the
5 following possible new policy.

6 In the information about CT dose provided
7 to users, manufacturers would have the option to
8 specify values of CTDI 100 in lieu of CTDI as it has
9 been previously defined.

10 As I described earlier, we believe that
11 CTDI 100 holds advantages of practicability of
12 measurement and fidelity to issue dose. If a
13 manufacturer were to elect to provide values of CTDI
14 100, the manufacturer would also need to provide
15 tables enabling a user to convert the CTDI 100 values
16 to the traditionally defined values of CTDI.

17 In the long term, regulations might be
18 proposed to resolve the number of the currently
19 outstanding issues that have been discussed in this
20 presentation. The first point is that one would want
21 to update the requirements for provision of dose
22 information.

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1 Terminology, indices, and ancillary
2 parameters, such a helical pitch, would be clearly
3 defined in terms of conveniently measurable quantities
4 reasonably related to system radiation output apropos
5 a typical procedure done in a given scanning mode.

6 Most likely CTDI 100 would be required for
7 axial scanning, but possibly a newly defined analog
8 might be required for helical scanning. Second, an
9 appropriately defined index or indices of patient
10 examination dose might be required for display.

11 The indices displayed ought to be
12 sensitive to the particular CT procedure a patient
13 receives, and for that purpose indicators displayed
14 might not necessarily be the same as those required in
15 the dose documentation.

16 In other words, we might want dose indices
17 displayed, one, to include the effect of table
18 increment or pitch reducing or increasing dose. Two,
19 to incorporate the range along a patient's body that
20 is covered in the scanning.

21 And, three, to reflect the repetitive
22 rotations of a CT fluoroscopic procedure or contrast

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1 study; or we might want to harmonize the displayed
2 indices with the two reference-value parameters
3 required in the European Union, namely dose-length
4 product, and CTDI W.

5 In any case, we will face some important
6 practical questions. Who will see the displayed
7 indices of dose? What will they do about what they
8 see?

9 If the values are displayed at the
10 operator's console only, will only the radiological
11 technologist see these values on a regular basis?
12 Will the values be archived in association with exam
13 images? Will the values be reviewed by anyone?
14 How can a quality assurance process be facilitated?

15 The third possible regulation is one that
16 might set limits on the axial extent of the radiation
17 field, vis-a-vis the length of the active detector
18 matrix.

19 The issues of over-beaming and efficient
20 use of radiation need to be considered carefully with
21 regard to optimal pre-patient collimation and
22 diagnostic efficacy.

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